#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

For: <b>ANTIBODIES TO PRO269 POLYPEPTIDES</b> )	Customer No. 77845
Filed: July 10, 2001	Attorney's Docket No. 39780-1618 P2C34
Application Serial No. 09/902,713	Confirmation No: 1320
Audrey GODDARD, et al.	Art Unit: 1646
In re application of:	Examiner: Kemmerer, Elizabeth

File Via EFS July 2, 2008

# ON APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES APPELLANTS' BRIEF

### MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 32613-1450

Dear Sir:

On November 7, 2007 and November 30, 2007, the Examiner made final rejections to pending Claims 39-43. A Notice of Appeal was filed therein on February 20, 2008 and an Appeal Brief was subsequently filed on May 20, 2008.

A Notification of Non-Compliant Appeal Brief was mailed June 5, 2008, which stated that the Appeal Brief did not fit with the criteria of 37 C.F.R. §41.37(c)(1)(v)). Specifically, the notification asserted that the summary of the claimed subject matter does not separately refer to the claims on appeal explicitly to the specification by page and line number and to the drawings, if any. The following amended Appeal Brief has been corrected to more clearly reference the claims and identify page and line numbers where appropriate in the Summary of Claimed Subject Matter (Section 5), as requested by the USPTO.

Appellants hereby resubmit only Section 5 of the Appeal Brief, both marked-up and clean versions of the amended section. The Board is requested to refer to the Appeal Brief submitted in its entirety dated May 20, 2008. This response to Non-Compliant Brief is timely filed within the one month time period set for response.

# **AMENDMENT TO THE BRIEF**

# V. SUMMARY OF CLAIMED SUBJECT MATTER

The invention claimed in the present application is related to an isolated antibody that specifically binds to the polypeptide of SEQ ID NO: 96 (Claim 39). The invention is further directed to an antibody that specifically binds to the polypeptide of SEQ ID NO: 96 which is a monoclonal antibody (Claim 40), a humanized antibody (Claim 41) or an antibody fragment[[.]] (Claims 40, 41 and Claim 42, respectively). The invention is further directed to an isolated antibody that specifically binds to the polypeptide of SEQ ID NO: 96 which is labeled. (Claim 43). The PRO269 gene was shown for the first time in the present application to be significantly amplified, ranging from 2.0-3.5 fold amplification in eight primary lung tumors or cell lines as compared to normal, non-cancerous human tissue controls (Example 92, in the specification at page 222, line 26, to page 235, line 3).

Support for the preparation and uses of antibodies are found throughout the specification, including, for example, pages 199-203. The preparation of antibodies is described in Example 57 (pages 199-200), while Example 59 (pages 200-201) describes the use of the antibodies for purifying the polypeptides to which they bind. Isolated antibodies are defined in the specification at page 76, line 38, to page 77, line 1. Support for monoclonal antibodies is found in the specification at, for example, page 73, lines 31-33. Support for humanized antibodies is found in the specification at, for example, page 141, line 15, to page 142, line 16. Support for antibody fragments is found in the specification at, for example, page 75, line 38 onwards to page 76, line 19. Support for labeled antibodies is found in the specification at, for example, page 77, lines 9-12.

The polypeptide of SEQ ID NO:96 is designated PRO269. The amino acid sequence of the native "PRO269" polypeptide and the nucleic acid sequence encoding this polypeptide (referred to in the present application as "DNA35705") are shown in the present specification as SEQ ID NOs: 96 and 95, respectively, and in Figures 36 and 35, described on page 60, lines 18-22. The full-length PRO269 polypeptide having the amino acid sequence of SEQ ID NO:96 is described in the specification at, for example, on page 12, line 30 to page 13, line 1, page 40, lines 1-11, page 103, lines 4-12, in Figure 36 and in SEQ ID NO:96 and the isolation of cDNA

clones encoding PRO269 of SEQ ID NO:95 is described in Example 15, pages [[xx]] <u>159-160</u> of the specification, as well as in Figure 35 and in SEQ ID NO:95.

Finally, The PRO 269 gene was shown for the first time in the present application to be significantly amplified, ranging from 2.0-3.5 fold amplification in eight primary lung tumors or cell lines as compared to normal, non-cancerous human tissue controls. Example 92, in the specification at page 222, line 26, to page 235, line 3, sets forth a 'Gene Amplification assay' which shows that the PRO269 gene is amplified in the genome of certain human lung cancers (see Table 9, page 230). The profiles of various primary lung tumors used for screening the PRO polypeptide compounds of the invention in the gene amplification assay are summarized on Table 8, page 227 of the specification.

# AMENDMENT TO THE BRIEF

# V. SUMMARY OF CLAIMED SUBJECT MATTER

The invention claimed in the present application is related to an isolated antibody that specifically binds to the polypeptide of SEQ ID NO: 96 (Claim 39). The invention is further directed to an antibody that specifically binds to the polypeptide of SEQ ID NO: 96 which is a monoclonal antibody (Claim 40), a humanized antibody (Claim 41) or an antibody fragment (Claim 42). The invention is further directed to an isolated antibody that specifically binds to the polypeptide of SEQ ID NO: 96 which is labeled. (Claim 43).

Support for the preparation and uses of antibodies are found throughout the specification, including, for example, pages 199-203. The preparation of antibodies is described in Example 57 (pages 199-200), while Example 59 (pages 200-201) describes the use of the antibodies for purifying the polypeptides to which they bind. Isolated antibodies are defined in the specification at page 76, line 38, to page 77, line 1. Support for monoclonal antibodies is found in the specification at, for example, page 73, lines 31-33. Support for humanized antibodies is found in the specification at, for example, page 141, line 15, to page 142, line 16. Support for antibody fragments is found in the specification at, for example, page 75, line 38 onwards to page 76, line 19. Support for labeled antibodies is found in the specification at, for example, page 77, lines 9-12.

The polypeptide of SEQ ID NO:96 is designated PRO269. The amino acid sequence of the native "PRO269" polypeptide and the nucleic acid sequence encoding this polypeptide (referred to in the present application as "DNA35705") are shown in the present specification as SEQ ID NOs: 96 and 95, respectively, and in Figures 36 and 35, described on page 60, lines 18-22. The full-length PRO269 polypeptide having the amino acid sequence of SEQ ID NO:96 is described in the specification at, for example, on page 12, line 30 to page 13, line 1, page 40, lines 1-11, page 103, lines 4-12, in Figure 36 and in SEQ ID NO:96 and the isolation of cDNA clones encoding PRO269 of SEQ ID NO:95 is described in Example 15, pages 159-160 of the specification, as well as in Figure 35 and in SEQ ID NO:95.

Finally, The PRO 269 gene was shown for the first time in the present application to be significantly amplified, ranging from 2.0-3.5 fold amplification in eight primary lung tumors

or cell lines as compared to normal, non-cancerous human tissue controls. Example 92, in the specification at page 222, line 26, to page 235, line 3, sets forth a 'Gene Amplification assay' which shows that the PRO269 gene is amplified in the genome of certain human lung cancers (see Table 9, page 230). The profiles of various primary lung tumors used for screening the PRO polypeptide compounds of the invention in the gene amplification assay are summarized on Table 8, page 227 of the specification.

# **CONCLUSION**

For the reasons given above, Appellants submit that the Appeal Brief submitted with regards to the instant application meets the requirements of 37 C.F.R.  $\S41.37(c)(1)(v)$ .

Accordingly, Appellants hereby request consideration by the Board of Patent Appeals and Interferences.

Please charge any additional fees, including fees for additional extension of time, or credit overpayment to Deposit Account No. <u>07-1700</u> (referencing Attorney's Docket No. <u>123851-181890 (GNE-1618P2C34)</u>).

Respectfully submitted,

Date: July 2, 2008

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